

DISPENSING OF DRUGS BY PUBLIC HEALTH NURSES

Part I

BACKGROUND INFORMATION

Revised April 2005

Updated: June 2009

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Introduction

In 1985, legislation passed by the North Carolina General Assembly granted registered nurses in local health department clinics limited authority to dispense drugs and devices. Codified as General Statute (G.S.) 90-85.34A, the law provides a unique opportunity for the public health community by increasing the number of options available to meet the needs of the health department patients. In addition, rules passed in 1987 which further explain the provisions of the statute are codified in the North Carolina Administrative Code as 21 NCAC 46.2400.

This is intended to serve as the primary training document for registered nurses who dispense drugs and devices in public health departments, as well as their pharmacist supervisors. As the first of two training documents, it is to be studied carefully by each trainee before the second document is reviewed.

The second document is a self-administered test to determine the trainee's understanding of the information provided in the first document.

Upon completion of both documents, approved trainers, including one pharmacist and one registered nurse, will provide classroom instruction.

Objectives

Upon completion of training, participants will be able to:

- 1 Demonstrate knowledge of the components of the laws and rules pertaining to the dispensing of drugs and devices by registered nurses in public health departments;
- 2 Understand the legal differences between prescription and non-prescription drugs and devices;
- 3 State the legal requirements for a prescription order
- 4 State the legal requirements for the packaging and labeling of drugs and devices;
- 5 State the legal requirements for records of drug and device dispensing activities;
- 6 Discuss the implications of failure to adhere to legal requirements for dispensing activities;
- 7 List the requirements for obtaining a pharmacy permit
- 8 Discuss the relationship between the pharmacist-manager, the local health department nurses, health department administration, and the North Carolina Board of Pharmacy;
- 9 Demonstrate proper packaging, labeling, and dispensing techniques;
- 10 Describe the requirements for the training of additional nurses in the local health department.

Enabling Legislation

The North Carolina Pharmacy Practice Act is found in Chapter 90, Article 4A of the North Carolina General Statutes. Among the many provisions of this act are specific statutes governing the practice of pharmacy, professional conduct, administrative requirements, and certain legal rights, responsibilities and empowerments. Supplemental to the Act, administrative rules found in the North Carolina Administrative Code at 21 NCAC 46 further describe the intent of each of the general statutes contained in the Act. Additionally, there are other statutes and rules found in law that directly affect the practice of pharmacy. In the text that follows, each component of the statutes and rules that affect the dispensing of drugs and devices by registered nurses in local health departments will be stated.

Pharmacy Law Update

Effective July 1, 2008, pharmacists must distribute with all prescriptions, information that patients call a toll-free telephone number (1-800-FDA-1088) to report adverse drug effects to the FDA. The final rule provides a number of ways by which this requirement can be accomplished (eg, vial sticker, preprinted vial cap, separate paper, in medication information.)

The required language is **“Call your doctor for medical advice about side effects. You may report side effects to FDA at 1-800-FDA-1088.”**

Definitions

IMPORTANT POINT (S): Multiple definitions for the same term may appear below depending upon differences in state and federal law. Citations referring to G.S. 90 or 21 NCAC 46 are found in the state Pharmacy Practice Act; citations referring to G.S. 106 are found in the state Food, Drug and Cosmetic Act; and citations referring to 21 USC are found in the federal Food, Drug and Cosmetic Act.

"Administer"- means the direct application of a drug to the body of a patient by injection, inhalation, ingestion or other means. [§ G.S. 90-85.3(a)]

"Dispense"- means preparing and packaging a prescription drug or device in a container and labeling the container with information required by State and federal law. Filling or refilling drug containers with prescription drugs for subsequent use by a patient is "dispensing." Providing quantities of unit dose prescription drugs for subsequent administration is "dispensing." [§ G.S. 90-85.3f]

"Deliver" -means the actual, constructive or attempted transfer of a drug, a device, or medical equipment from one person to another. [§ G.S. 90-85.3d]

"Drug" -means:

- (1) Any article recognized as a drug in the United States Pharmacopeia, or in any other drug compendium or any supplement thereto, or an article recognized as a drug by the United States Food and Drug Administration;
- (2) Any article, other than food or devices, intended for use in the diagnosis, cure, mitigation, treatment or prevention of disease in man or other animals;
- (3) Any article, other than food or devices, intended to affect the structure or any function of the body of man or other animals; and
- (4) Any article intended for use as a component of any articles specified in clauses 1, 2, or 3 of this subsection. [§ G.S. 90-85.3g]

"Drug"- means

- (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and
- (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and
- (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and
- (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 403(r)(1)(B) and 403(r)(3) of this title or sections 403(r)(1)(B) and 403(r)(5)(D) of this title, is made in accordance with the requirements of section 403(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for which a truthful and not misleading

statement is made in accordance with section 403(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement. [21 USC 321t(g)(l)]

"Device"- means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent or other similar or related article including any component part or accessory, whose label or labeling bears the statement "Caution: federal law requires dispensing by or on the order of a physician.", or "Rx Only". The term does not include:

- (1) Devices used in the normal course of treating patients by health care facilities and agencies licensed under Chapter 131 E or Article 2 of Chapter 122C of the General Statutes;
- (2) Devices used or provided in the treatment of patients by medical doctors, dentists, physical therapists, occupational therapists, speech pathologists, optometrists, chiropractors, podiatrists, and nurses licensed under Chapter 90 of the General Statutes, provided they do not dispense devices used to administer or dispense drugs. [§ G.S. 90-85.3e]

"Emancipated minor"- means any person under the age of 18 who is or has been married or who is or has been a parent; or whose parents or guardians have surrendered their rights to the minor's services and earnings as well as their right to custody and control of the minor's person; or who has been emancipated by an appropriate court order. [§ G.S. 90-85.3h]

"Equivalent drug product"- means a drug product which has the same established name, active ingredient, strength, quantity, and dosage form, and which is therapeutically equivalent to the drug product identified in the prescription; [§ G. S. 90-85.27(1)]

"Health care provider"- means any licensed health care professional; any agent or employee of any health care institution, health care insurer, health care professional school; or a member of any allied health profession. [§ G.S. 90-85.3i]

"Label"- means a display of written, printed or graphic matter upon the immediate or outside container of any drug. [§ G.S. 90-85.3j]

"Labeling"- means preparing and affixing a label to any drug container, exclusive of labeling by a manufacturer, packer or distributor of a nonprescription drug or a commercially packaged prescription drug or device. [§ G.S. 90-85.3k]

"License"-means a license to practice pharmacy including a renewal license issued by the Board. [§ G.S. 90-85.3l]

"Narrow therapeutic index drugs" - means those pharmaceuticals having a narrowly defined range between risk and benefit. Such drugs have less than a twofold difference in the minimum toxic concentration and minimum effective concentration in the blood or are those drug product formulations that exhibit limited or erratic absorption, formulation-dependent bioavailability, and wide inpatient pharmacokinetic variability that require blood-level monitoring. Drugs identified as having narrow therapeutic indices shall be designated by the North Carolina Secretary of Health and Human Services upon the advice of the State Health Director, North Carolina Board of Pharmacy, and North Carolina Medical Board, as narrow therapeutic index drugs and shall be subject to the provisions of G.S. 90-85.28(b1). The North Carolina Board of Pharmacy shall submit the list of narrow therapeutic index drugs to the Codifier of Rules, in a timely fashion for publication in January of each year in the North Carolina Register. [§ G. S. 90-85.27(4a)]

****IMPORTANT POINT****

Currently, there are no narrow therapeutic index drugs included in the NC Health Department formularies or approved list of drugs to be dispensed by RN's.

"Nonprescription Drug" (Also known as Over-the-Counter Drug)- means drugs, not requiring a prescription, which are recognized among experts to be safe and effective for use. [21 CFR 330.10]

"Permit" -means a permit to operate a pharmacy, deliver medical equipment, or dispense devices, including a renewal license issued by the Board. [§ G.S. 90-85.3m]

"Person" -means an individual, corporation, partnership, association, unit of government, or other legal entity. [§ G.S. 90-85.3n]

"Person in loco parentis" -means the person who has assumed parental responsibilities for a child. [§ G.S. 90-85.3o]

"Pharmacist"- means a person licensed under this Article to practice pharmacy. [§ G.S. 90-85.3p]

"Pharmacy" means any place where prescription drugs are dispensed or compounded. [§ G.S. 90-85.3q]

'Pharmacy personnel' means pharmacists and pharmacy technicians. [§ G.S. 90-85.3(q1)]

'Pharmacy technician' means an unlicensed person who, under the supervision of a pharmacist, perform technical functions to assist the pharmacist in preparing and dispensing prescription medications and is subject to the registration requirements under G.S. 90-85.15A. [§ G.S. 90-85.3(q2)]

"Practice of pharmacy"- means the responsibility for: interpreting and evaluating drug orders, including prescription orders; compounding, dispensing and labeling prescription drugs and devices; properly and safely storing drugs and devices; maintaining proper records; and controlling pharmacy goods and services.

A pharmacist may advise and educate patients and health care providers concerning therapeutic values, content, uses and significant problems of drugs and devices; assess, record and report adverse drug and device reactions; take and record patient histories relating to drug and device therapy; monitor, record and report drug therapy and device usage; perform drug utilization reviews; and participate in drug and drug source selection and device and device source selection as provided in G.S. 90-85.27 through G.S. 90-85.31.

A pharmacist who has received special training may be authorized and permitted to administer drugs pursuant to a specific prescription order in accordance with rules adopted by each of the Boards of Pharmacy, the Board of Nursing, and the North Carolina Medical Board. The rules shall be designed to ensure the safety and health of the patients for whom such drugs are administered. An approved clinical pharmacist practitioner may collaborate with physicians in determining the appropriate health care for a patient, subject to the provisions of G.S. 90-18.3. [§ G.S. 90-85.3r]

"Prescriber"- means anyone authorized to prescribe drugs pursuant to the laws of this State. [§ G. S. 90-85.27(5)]

"Prescription drug" means a drug that under federal law is required, prior to being dispensed or delivered, to be labeled with the following statement: "Caution: Federal law prohibits dispensing without prescription." [§ G.S. 90-85.3s]
and

A drug intended for use by man which—

(A) because of its toxicity or other potentiality for harmful effect, or the method of its use, or the collateral measures necessary to its use, is not safe for use except under the supervision of a practitioner licensed by law to administer such drug; or

(B) is limited by an approved application under section 355 of this title to use under the professional supervision of a practitioner licensed by law to administer such drug.

[21 USC § 353b(1)]

"Prescription order" means a written or verbal order for a prescription drug, prescription device, or pharmaceutical service from a person authorized by law to prescribe such drug, device, or service. A prescription order includes an order entered in a chart or other medical record of a patient. [§ G.S. 90-85.3t]

"Unit dose medication system" means a system in which each dose of medication is individually packaged in a properly sealed and properly labeled container.
. [§ G.S. 90-85.3u]

PHARMACY LAWS OF NORTH CAROLINA

General Statutes

Chapter 90, Article 4A

Chapter 90.

MEDICINE AND ALLIED OCCUPATIONS.

§ 90-85.2. Legislative findings.

The General Assembly of North Carolina finds that mandatory licensure of all who engage in the practice of pharmacy is necessary to insure minimum standards of competency and to protect the public from those who might otherwise present a danger to the public health, safety and welfare.

§ 90-85.32 Rules pertaining to filling, refilling, transfer and mail or common-carrier delivery of prescription orders.

- (a) Except as otherwise provided in this section, the Board may adopt rules governing the filling, refilling and transfer of prescription orders not inconsistent with other provisions of law regarding the distribution of drugs and devices. The rules shall assure the safe and secure distribution of drugs and devices. Prescriptions marked PRN shall not be refilled more than one year after the date issued by the prescriber unless otherwise specified.
- (b) Notwithstanding G.S. 90-85.6 the Board shall not adopt rules pertaining to the shipment, mailing or other manner of delivery of dispensed legend drugs that are more restrictive than federal statutes or regulations governing the delivery of prescription medication by mail or common carrier.

§ 90-85.34. Unique pharmacy practice.

Consistent with the provisions of this Article, the Board may regulate unique pharmacy practices including, but not limited to, nuclear pharmacy and clinical pharmacy, to ensure the best interests of patient health and safety

***IMPORTANT POINT (S).** These statutes clearly empower the Board of Pharmacy to play an important part in protecting the public health of North Carolinians. The statutes also empower others with responsibilities for protecting the public health and include: the state Boards of Medicine, Nursing, Dentistry, Optometry, Veterinary Medicine, the state Departments of Health and Human Services, Agriculture, and others, as well as local and federal agencies. The extent to which the Board of Pharmacy can protect the public health is limited by additional statutes, regulations, and policies, as well as similar powers granted to other boards, commissions, and agencies.

§ 90-85.34.A. Public health pharmacy practice.

- (a) A registered nurse in a local health department clinic may dispense prescription drugs and devices, other than controlled substances as defined in G.S 90-87, under the following conditions:
- (1) The registered nurse has training acceptable to the Board in the labeling and packaging of prescription drugs and devices;
 - (2) Dispensing by the registered nurse shall occur only at a local health department clinic;
 - (3) Only prescription drugs and devices contained in a formulary recommended by the Department of Health and Human Resources and approved by the Board shall be dispensed;
 - (4) The local health department clinic shall obtain a pharmacy permit in accordance with G.S. 90-85.21;
 - (5) Written procedures for the storage, packaging, labeling and delivery of prescription drugs and devices shall be approved by the Board; and
 - (6) The pharmacist-manager, or another pharmacist at his direction, shall review dispensing records at least weekly, provide consultation where appropriate, and be responsible to the Board for all dispensing activity at the local health department clinic.
- (b) This section is applicable only to prescriptions issued on behalf of persons receiving local health department clinic services and issued by an individual authorized by law to prescribe drugs and devices.
- (c) This section does not affect the practice of nurse practitioners pursuant to G..S. 90-18.2 or of physician assistants pursuant to G.S. 90-18.1.

IMPORTANT POINTS

- **The statute specifically grants dispensing privileges to registered nurses only.** It does not grant dispensing privileges to licensed practical nurses, practical nurses, nurse's aides, nursing assistants, etc. It does not apply to nurse practitioners or physician assistants. (Rules for dispensing for nurse practitioners and physician's assistants are found at 21 NCAC 46.1700-.1706)
- **The nurse must be working in a local health department clinic,** the operation of which is the direct responsibility of a local board of health and the local health director. **The person to whom a prescription is dispensed pursuant to this statute must be a patient of the local health department.** Customarily, this

means that the local health department has opened a chart on this patient and is responsible for health and/or medical interventions.

- The term “dispense” is defined in G.S. 90-85.3(f) as “..preparing and packaging a prescription drug or device in a container and labeling the container with information required by State and federal law. **Filling or refilling drug containers with prescription drugs for subsequent use by a patient is "dispensing."** Providing quantities of unit dose prescription drugs for subsequent administration is "dispensing."
- This statute governs the dispensing of prescription drugs and devices only. **Prescription drugs** are products whose manufacturers are required by federal law to label each stock bottle or package with one of the following statements: “Caution: Federal law prohibits dispensing without prescription” or “Rx only”. **Prescription devices** are products whose manufacturers are required by federal law to label each stock package: “Caution: Federal law requires dispensing by or on the order of a physician.”
- **The statute prohibits the dispensing of controlled substances of any kind by registered nurses.** Controlled substances are those licit and illicit drugs listed in the federal controlled substance schedules I through V, and/or the state controlled substances schedules I through VI. Among the most common licit drugs included in the controlled substance schedules are narcotics, amphetamines, barbiturates, certain sedatives and tranquilizers, and codeine-containing cough preparations.
- **The statute does not require registered nurses in local health department clinics to dispense.** The dispensing privilege is optional. Local health department policies and procedures should be followed.
- **A pharmacy permit is required for each geographic site where dispensing occurs.**
- **The Board generally reviews the written procedures for storage, packaging and labeling at the time a pharmacy permit application is considered.**

§ 90-85.35. Availability of patient records.

Pharmacists employed in health care facilities shall have access to patient records maintained by those facilities when necessary for the pharmacist to provide pharmaceutical services. The pharmacist shall make appropriate entries in patient records.

§ 90-85.25. Disasters and emergencies.

- (a) In the event of an occurrence which the Governor of the State of North Carolina has declared a disaster or when the Governor has declared a state of emergency, or in the event of an occurrence for which a county or municipality has enacted an ordinance to deal with states of emergency under G.S. 14-288.12, 14-288.13, or 14-288.14 or to protect the public health, safety or welfare of its citizens under G.S. 160-A-174(a) or G.S. 153A-121(a), as applicable, the Board may waive the requirements of this Article in order to permit the provision of drugs, devices and professional services to the public.
- (b) The pharmacist in charge of a pharmacy shall report within 10 days to the Board any disaster, accident, theft or emergency which may affect the strength, purity or labeling of drugs and devices in the pharmacy.

IMPORTANT POINT

This section provides that the Board of Pharmacy may take action to permit the relocation of pharmacy sites, including public health department sites, and assist local government, pharmacies, and health care facilities in meeting the needs of the public once an emergency or disaster has been declared by the appropriate authorities at the state or local level.

21 North Carolina Administrative Code 46

(21 NCAC 46)

.2401 MEDICATION IN HEALTH DEPARTMENTS

A registered nurse employed by a local health department may dispense prescription drugs or devices under the following conditions:

- (1) Drugs or devices may be dispensed only to health department patients;
- (2) No drugs or devices may be dispensed except at health department clinics;
- (3) The health department shall secure the services of a pharmacist-manager who shall be responsible for developing and supervising a system of control and accountability of all drugs dispensed from the health department;
- (4) Only the general categories of drugs or devices listed in Rule .2403 may be dispensed by a health department registered nurse;
- (5) All drugs or devices dispensed pursuant to G.S. 90-85.34A and these rules shall be packaged in suitable safety-closure containers, where appropriate, and shall be properly labeled (including necessary auxiliary labels) so as to provide information necessary for use and all other information required by state and federal law;
- (6) A suitable and perpetual record of drugs or devices dispensed shall be maintained in the health department. The pharmacist-manager shall verify the accuracy of the records at least weekly, and where health department personnel dispense to 30 or more patients in a 24-hour period per dispensing site, the pharmacist-manager shall verify the accuracy of the records within 24 hours after dispensing occurs;
- (7) The duties of the pharmacist-manager set out in Paragraphs (1) through (6) in this Rule may be delegated to a pharmacist licensed by the Board. The pharmacist-manager shall remain personally responsible for compliance with all statutes, rules, and regulations governing the practice of pharmacy and dispensing of drugs.

.2402 TRAINING OF HEALTH DEPARTMENT NURSES

- (a) No registered nurse may dispense drugs or devices or perform any duties pursuant to G.S. 90-85.34A prior to satisfactory completion of training acceptable to the Board. The Board may require registered nurses to complete additional training regarding substantive changes in the law governing labeling and packaging of prescription drugs and devices.
- (b) Proposed curricula for initial training for registered nurses secured by health departments must be submitted to the Board for its approval no later than 60 days prior to the date training is to commence. No registered nurses may be enrolled in any such proposed training course until written Board approval is obtained. Initial training must include, but need not be limited to, instruction in labeling and packaging of prescription drugs and devices.

(c) Written proposals shall be sent to the Board's offices, and shall include the following information:

- (1) description of topics or courses to be covered;
- (2) instructor for each topic or course, and his or her qualifications and credentials;
- (3) anticipated duration of each topic or course.

.2403 DRUGS AND DEVICES TO BE DISPENSED (i.e., the Formulary)

(a) Pursuant to the provisions of G.S. 90-85.34A(a)(3), prescription drugs and devices included in the following general categories may be dispensed by registered nurses in local health department clinics when prescribed for the indicated conditions:

- (1) Anti-tuberculosis drugs, as defined by the latest edition of Drug Facts and Comparisons, as published by Facts and Comparison Div., J.B. Lippincott Co., or as recommended by the Tuberculosis Control Branch of the North Carolina Division of Health Services, when used for the treatment and control of tuberculosis;
- (2) Anti-infective agents used in the control of sexually-transmitted diseases as recommended by the United States Centers for Disease Control;
- (3) Natural or synthetic hormones and contraceptive devices when used for the prevention of pregnancy;
- (4) Topical preparations for the treatment of lice, scabies, impetigo, diaper rash, vaginitis, and related skin conditions; and
- (5) Vitamin and mineral supplements.

(b) Regardless of the provisions set out in this Rule, no drug defined as a controlled substance by the United States Controlled Substances Act, 21 U.S. Code 801 through 904, or regulations enacted pursuant to that Act, 21 CFR 1300 through 1308, or by the North Carolina Controlled Substances Act, G.S. 90-86 through 90-113.8, may be dispensed by registered nurses pursuant to G.S. 90-85.34A.

POISON PREVENTION PACKAGING ACT OF 1970 (PPPA)

The PPPA authorizes the Consumer Product Safety Commission to establish standards for “special packaging” of substances that may cause illness or injury to small children.

It is intended to reduce poisonings among small children. Items covered by the Act must be packaged in containers that cannot be opened by 80% of children under the age of five, but that can be opened by 90% of adults.

With respect to items that may be dispensed, the Act covers the following:

- 1) Human prescription drugs in oral dosage forms, except oral contraceptives in manufacturers' memory-aid dispenser packages, nitroglycerin, unit-dose packaged drugs, and a few other exceptions;
- (1) All controlled substances in oral dosage forms;
- (2) Aspirin products, except for certain effervescent and powder forms;
- (3) Iron-containing oral products, including dietary supplements; and
- (4) Acetaminophen products, except for certain effervescent and powder forms.

The consumer may request that non-safety packaging be used and may give a blanket waiver regarding all of his/her prescriptions. Such authorization should be received in writing.

Safety closures can lose their effectiveness with repeated use, therefore new containers must be used when refilling prescriptions. However, if glass containers are used, the Act permits replacing the cap only.

The manufacturer's original package, with appropriate labeling, may be dispensed directly to the consumer if it meets safety-packaging requirements.

In April, 2001, the Code of Federal Regulations, (Title 21 CFR 111.50.) further restricted the packaging requirements of iron-containing products as follows:

The use of iron and iron salts offered in solid oral dosage form (e.g., tablets or capsules), and containing 30 milligrams or more of iron per dosage unit, is safe and in accordance with current good manufacturing practice only when such supplements are packaged in unit-dose packaging. "Unit-dose packaging" means a method of packaging a product into a non-reusable container designed to hold a single dosage unit intended for administration directly from that container, irrespective of whether the recommended dose is one or more than one of these units. The term "dosage unit" means the individual physical unit of the product (e.g., tablets or capsules). Iron-containing products that are subject to this regulation are also subject to child-resistant special packaging requirements.

PRESCRIPTION: DRUG ORDER REQUIREMENTS

(a) Prescription orders shall include, but not be limited to:

- (1) date of issuance;

- (2) name and address of patient;
 - (3) name, address and telephone number of prescriber except that indication of the name of the prescriber is sufficient if a data file specified in (b) of this Rule is current and in effect;
 - (4) Drug Enforcement Agency (DEA) number of prescriber in the case of controlled substances;
 - (5) name, strength, dosage form and quantity of drug prescribed;
 - (6) refills if authorized or, in institutions, the stop date;
 - (7) route of administration of drug prescribed; and
 - (8) directions for use.
- (b) Information in Subparagraphs (a)(2), (a)(3), (a)(4), (a)(6) and (a)(7) may be stored in a readily retrievable data file specifically compiled for use in the pharmacy, which is not a commercial publication, in lieu of the requirements of the named Subparagraphs.
[21 NCAC 46.2301]

Any drug the label of which bears the statement "Caution: Federal law prohibits dispensing without a prescription," or "Rx only", (i.e. prescription drugs), shall be dispensed only:

- a. Upon a written prescription of a practitioner licensed by law to administer such drug, or authorized to issue orders pursuant to G.S. 90-87(23)(a), provided that the written prescription must bear the printed or stamped name, address, telephone number and DEA number of the prescriber in addition to his legal signature, or
- b. Upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or
- c. By refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. If any prescription for such drug does not indicate the times it may be refilled, if any, such prescription may not be refilled unless the pharmacist is subsequently authorized to do so by the practitioner.

The act of dispensing a drug contrary to the provisions of this subdivision shall be deemed to be an act which results in a drug being misbranded while held for sale.

[G.S. 106.134.1(4)]

A prescription drug shall be dispensed only;

- (i) upon a written prescription of a practitioner licensed by law to administer such drug, or
- (ii) upon an oral prescription of such practitioner which is reduced promptly to writing and filed by the pharmacist, or
- (iii) by refilling any such written or oral prescription if such refilling is authorized by the prescriber either in the original prescription or by oral order which is reduced promptly to writing and filed by the pharmacist. The act of dispensing a drug contrary to the provisions of this paragraph shall be deemed to be an act which results in the drug being misbranded while held for sale. [21 USC 353 (b)(1)(c)]

All of the above requirements shall apply to nonprescription drugs when they are to be removed from the manufacturer's original container and dispensed to a patient.

PRESCRIPTION LABEL AND PACKAGING

A label shall be affixed to the container of a prescription drug and shall contain all of the following information:

- (1) The name of the patient;
- (2) The name and address of the pharmacy;
- (3) The phrase “Filled by _____” or “Dispensed by _____”, with the name of the practitioner who dispensed the prescription appearing in the blank;
- (4) The serial number and date of the prescription or of its filling;
- (5) The name of the prescriber;
- (6) The directions for use;
- (7) The name and strength of the drug (unless otherwise directed by the prescriber);
also, the brand name of any drug product dispensed, or in the absence of a brand name, the established name;

*****Effective January 1, 2006*****

The generic name of the drug must be listed on the label, even if the generic drug is unavailable to dispense, or even if the substitution of a generic drug is not permitted. [21 NCAC 46.1818]

- (8) The discard date when dispensed in a container other than the manufacturer’s original container. The discard date shall be the earlier of one year from the date dispensed or the manufacturer’s expiration date, whichever is earlier. The label shall not obscure the expiration date and storage statement when the product is dispensed in the manufacturer’s original container;
- (9) Cautionary statements, if any, contained in such prescriptions; and

(10) Necessary auxiliary labels.

[G.S. 105-134.1][21 USC 353][G.S. 90-85.29][21 NCAC 46.2401]

All of the above requirements apply to nonprescription drugs also, when removed from the manufacturer's original container and dispensed to a patient.

Prescription label

The prescription label of every drug product dispensed shall contain the brand name of any drug product dispensed, or in the absence of a brand name, the established name. The prescription drug label of every drug product dispensed shall:

- (1) Contain the discard date when dispensed in a container other than the manufacturer's original container. The discard date shall be the earlier of one year from the date dispensed or the manufacturer's expiration date, whichever is earlier, and
- (2) Not obscure the expiration date and storage statement when the product is dispensed in the manufacturer's original container.
- (3) As used in this section, "expiration date" means the expiration date printed on the original manufacturer's container, and "discard date" means the date after which the drug product dispensed in a container other than the original manufacturer's container shall not be used. Nothing in this section shall impose liability on the dispensing pharmacist or the prescriber for damages related to or caused by a drug product that loses its effectiveness prior to the expiration or disposal date displayed by the pharmacist or prescriber. [G.S. § 90-85.29]

21 NCAC 46 .1818 PRESCRIPTION LABELS **EFFECTIVE JANUARY 1, 2006

Prescription labels shall list at a minimum the generic name of the drug, even if the generic drug is unavailable to dispense or even if the substitution of a generic drug is not authorized.

Re-packaging

When drugs are removed from their original manufacturer-supplied container and repackaged into dispensing containers to be held as bulk stock prior to being dispensed to a specific patient, the U.S. Food and Drug Administration (FDA) has recommended (in part) that labels containing the following information from the manufacturer's original container be affixed to each dispensing container:

1. The proprietary (brand) or generic name of the drug;
2. The quantity of active ingredient per dose unit;
3. The name of the manufacturer, packer, or distributor;
4. The lot or control number; and
5. The expiration date.

§ 90-85.33. Unit dose medication systems.

The Board may adopt regulations governing pharmacists providing unit dose medication systems. The regulations shall ensure the safe and proper distribution of drugs in the patients best health interests.

PRESCRIPTION RECORDS

§ 90-85.26. Prescription orders preserved.

Every pharmacist-manager of a pharmacy shall maintain, for at least three years* the original of every prescription order and refill compounded or dispensed at the pharmacy except for prescription orders recorded in a patient's medical record. An automated data processing system may be used for the storage and retrieval of refill information for prescriptions pursuant to the regulations of the Board.

§ 90-85.30. Prescription record.

The pharmacy file copy of every prescription shall include the brand or trade name, if any, or the established name and the manufacturer of the drug product dispensed.

Records of Dispensing

- (a) Records of dispensing for original and refill prescriptions are to be made and kept by pharmacies for three years* and shall include, but are not limited to:
- (1) quantity dispensed, if quantity of refill is different than quantity of original;
 - (2) date of dispensing;
 - (3) serial number (or equivalent in an institution);
 - (4) the identification of the pharmacist responsible for dispensing;
 - (5) records of refills to date;
 - (6) documentation of satisfaction of state requirements for drug selection.
- (b) Records in institutional pharmacies may be made and kept as part of the patient's medical record.[21 NCAC 46.2302]

Records of prescription filling and refilling

In a pharmacy with a manual system, the dispensing pharmacist shall indicate by date and initial the filling or refilling of a prescription on the document. In a pharmacy with a computer or data system, a designation of the dispensing pharmacist accompanied by the daily signature of the pharmacist filling or refilling each prescription is required as noted in Rule .2304(3)(a) or (3)(b). Information must be kept for three years. This does not preclude the use of unlicensed personnel entering information in a data system provided that supervision is maintained pursuant to Board rules.
[21 NCAC 46.2303]

Security

To maintain the confidentiality of patients' prescription orders, there must exist adequate safeguards or security of the records. [21 NCAC 46.2305]

Automated data processing systems

An automated data processing system may be employed as a record-keeping system if the following conditions are met:

* For local health departments, the requirement for retention is **5 years**, these guidelines can be accessed at <http://www.ah.dcr.state.nc.us/records/local/default.htm>.

- (1) The system shall have the capability of producing sight-readable documents of all original and refilled prescription information. The term “sight-readable” means that a regulatory agent shall be able to examine the record and read the information. In the case of administrative proceedings before the Board, records must be provided in a readable paper printout form.
- (2) Such information shall include, but not be limited to the prescription requirements and records of dispensing as indicated in Rules .2301 and .2302 of this Section.
- (3) The individual pharmacist responsible for completeness and accuracy of the entries to the system must provide documentation of the fact that prescription information entered into the computer is correct. In documenting this information, the pharmacist shall have the option of either:
 - (a) providing a printout of each day's prescription information. That printout shall be dated and the individual pharmacist shall verify that the information indicated is correct and sign the printout in the same manner as a check or legal document (e.g. J.H. Smith, or John H. Smith). Such printout must be maintained three years from the date of last dispensing; or
 - (b) maintaining a log book, or separate file, in which each individual pharmacist involved in such dispensing shall sign a statement each day attesting to the fact that the prescription information entered into the computer that day has been reviewed and is correct as shown. Such a book or file must be maintained at the pharmacy employing such a system for a period of three years after the date of last dispensing.
- (4) Documentation in Paragraph (3) of this Rule must be provided in the pharmacy within 72 hours of date of dispensing.
 - (1) An auxiliary record-keeping system shall be established for the documentation of refills if the automated data processing system is inoperative for any reason. When the automated data processing system is restored to operation, the information regarding prescriptions filled, refilled or transferred during the inoperative period shall be entered into the automated data processing system within the time equal to the number of inoperative days times three; for example, if the system were inoperative for five days then all interim data shall be entered within 15 days of the last inoperative day. However, nothing in this Paragraph shall preclude the pharmacist from using professional judgment for the benefit of a patient's health and safety. The auxiliary record keeping system shall be backed up at least weekly.
 - (2) A pharmacy shall make arrangements with the supplier of data processing services or materials to assure that the pharmacy continues to have adequate and complete prescription and dispensing records if the relationship with such supplier is terminated for any reason. A pharmacy shall assure continuity in the maintenance of records.
 - (3) A current version of drug interactions software shall be used and policies and procedures shall be established to address overriding the interactions prompt.

{21 NCAC 46.2304}

Availability of patient records

Pharmacists employed in health care facilities shall have access to patient records maintained by those facilities when necessary for the pharmacist to provide pharmaceutical services. The pharmacist shall make appropriate entries in patient records. [G.S.90-85.35]

All records pertaining to the filling and refilling of prescriptions shall be available to designated employees of the Board during normal business hours.
[21 NCAC 46.1803]

§ 90-85.36. Availability of pharmacy records.

- (a) Except as provided in subsections (b) and (c) below, written prescription orders on file in a pharmacy or other place where prescriptions are dispensed are not public records and any person having custody of or access to the prescription orders may divulge the contents or provide a copy only to the following persons:
 - (1) An adult patient for whom the prescription was issued or a person who is legally appointed guardian of that person;
 - (2) An emancipated minor patient for whom the prescription order was issued or a person who is the legally appointed guardian of that patient;
 - (3) An unemancipated minor patient for whom the prescription order was issued when the minor's consent is sufficient to authorize treatment of the condition for which the prescription was issued;
 - (4) A parent or person in loco parentis of an unemancipated minor patient for whom the prescription order was issued when the minor's consent is not sufficient to authorize treatment for the condition for which the prescription is issued;
 - (5) The licensed practitioner who issued the prescription;
 - (6) The licensed practitioner who is treating the patient for whom the prescription was issued;
 - (7) A pharmacist who is providing pharmacy services to the patient for whom the prescription was issued;
 - (8) Anyone who presents a written authorization for the release of pharmacy information signed by the patient or his legal representative;
 - (9) Any person authorized by subpoena, court order or statute;

- (10) Any firm, association, partnership, business trust, corporation or company charged by law or by contract with the responsibility of providing for or paying for medical care for the patient for whom the prescription order was issued;
 - (11) A member or designated employee of the Board;
 - (12) The executor, administrator or spouse of a deceased patient for whom the prescription order was issued;
 - (13) Researchers and surveyors who have approval from the Board. The Board shall issue this approval when it determines that there are adequate safeguards to protect the confidentiality of the information contained in the prescription orders and that the researchers or surveyors will not publicly disclose any information that identifies any person; or
 - (14) The person owning the pharmacy or his authorized agent.
- (b) A pharmacist may disclose any information to any person only when he reasonably determines that the disclosure is necessary to protect the life or health of any person.
 - (c) Records required to be kept by G.5. 90-93(d) (Schedule V) are not public records and shall be disclosed at the pharmacist's discretion.

§ 90-85.26. Prescription orders preserved.

Every pharmacist-manager of a pharmacy shall maintain for at least three years the original of every prescription order and refill compounded or dispensed at the pharmacy except for prescription orders recorded in a patient's medical record. An automated data processing system may be used for the storage and retrieval of refill information for prescriptions pursuant to the regulations of the Board.

Health Insurance Portability and Accountability Act of 1996

Under HIPAA regulations, all prescription records and dispensing information are considered protected health information (PHI) and are subject to all guidelines concerning PHI.

DRUG PRODUCT SELECTION

§ 90-85.28. Selection by pharmacists permissible; prescriber may permit or prohibit selection; price limit on selected drugs.

a) **A pharmacist dispensing a prescription for a drug product prescribed by its brand name may select any equivalent drug product which meets the following standards:**

- (1) The manufacturer's name and the distributor's name, if different from the manufacturer's name, shall appear on the label of the stock package;
- (2) It shall be manufactured in accordance with current good manufacturing practices;
- (3) Effective January 1, 1982, all oral solid dosage forms shall have a logo, or other identification mark, or the product name to identify the manufacturer or distributor;
- (4) The manufacturer shall have adequate provisions for drug recall; and
- (5) The manufacturer shall have adequate provisions for return of outdated drugs, through his distributor or otherwise.

(b) **The pharmacist shall not select an equivalent drug product if the prescriber instructs otherwise by one of the following methods:**

- (1) A prescription form shall be preprinted or stamped with two signature lines at the bottom of the form which read:

.....
Product Selection Permitted	Dispense as Written

On this form, the prescriber shall communicate his instructions to the pharmacist by signing the appropriate line.

- (2) In the event the preprinted or stamped prescription form specified in (b)(1) is not readily available, the prescriber may hand write "Dispense as Written" or words or abbreviations of the same meaning on a prescription form.
- (3) When ordering a prescription orally, the prescriber shall specify either that the prescribed drug product be dispensed as written or that product selection is permitted. The pharmacist shall note the instructions on the file copy of the prescription and retain the prescription form for the period prescribed by law.

(b1) **A prescription for a narrow therapeutic index drug shall be refilled using only the same drug product by the same manufacturer that the pharmacist last dispensed under the prescription, unless the prescriber is notified by the pharmacist prior to the dispensing of another manufacturer's product, and the prescriber and the patient give documented consent to the dispensing of the other manufacturer's product.** For purposes of this subsection, the term "refilled" shall include a new prescription written at the expiration of a prescription which continues the patient's therapy on a narrow therapeutic index drug.

(c) **The pharmacist shall not select an equivalent drug product unless its price to the purchaser is less than the price of the prescribed drug product.**

**** IMPORTANT POINT ****

Currently, there are no narrow therapeutic index drugs included in the NC Health Department formularies or approved list of drugs to be dispensed by RN's.

§ 90-85.31. Prescriber and pharmacist liability not extended.

The selection of an equivalent drug product pursuant to this Article shall impose no greater liability upon the pharmacist for selecting the dispensed drug product or upon the prescriber of the same than would be incurred by either for dispensing the drug product specified in the prescription.

"Equivalent drug product"- means a drug product which has the same established name, active ingredient, strength, quantity, and dosage form, and which is therapeutically equivalent to the drug product identified in the prescription;
[§ G. S. 90-85.27(1)]

Adequate provisions for return of outdated drugs both full and partial containers as provided in G.S. 90-85.28(a)(5) means that drugs can be returned up to six months after the labeled expiration date for prompt full credit or replacement. A finding by the Board that a manufacturer does not meet this standard will cause that manufacturer's products to be ineligible for use in product selection. [21 NCAC 46.2901]

The NC General Assembly authorizes and mandates that pharmacists participating in the Medicaid Assistance Program (**Medicaid**) substitute generic drugs for brand or trade name drugs unless the prescriber specifically orders the brand name drug by signing the **“Dispense as Written”** line and writing **“Brand Medically Necessary”** in his/her own handwriting on the face of the prescription.

PATIENT COUNSELING

(a) **"Patient Counseling"** shall mean the effective communication of information, as defined in this Rule, to the patient or representative in order to improve

therapeutic outcomes by maximizing proper use of prescription medications, devices, and medical equipment. All provisions of this Rule shall apply to device and medical equipment permit holders, except Subparagraph (a)(8) of this Rule and except where otherwise noted. Specific areas of patient counseling include, but are not limited to, those matters listed in this Rule that in the exercise of the pharmacist's or device and medical equipment permit holder's professional judgment are considered significant:

- (1) name, description, and purpose of the medication;**
 - (2) route, dosage, administration, and continuity of therapy;**
 - (3) special directions for use by the patient;**
 - (4) common severe side or adverse effects or interactions and therapeutic contraindications that may be encountered, including their avoidance, and the action required if they occur;**
 - (5) techniques for self-monitoring drug therapy;**
 - (6) proper storage;**
 - (7) prescription refill information; and**
 - (8) action to be taken in the event of a missed dose.**
- (b) An offer to counsel shall be made on new or transfer prescriptions at the time the prescription is dispensed or delivered to the patient or representative.** Ancillary personnel may make the offer to counsel, but the pharmacist must personally conduct counseling if the offer is accepted. Counseling by device and medical equipment permit holders must be conducted by personnel proficient in explaining and demonstrating the safe and proper use of devices and equipment. The person in charge shall be responsible for ensuring that all personnel conducting counseling are proficient in explaining and demonstrating the safe and proper use of devices and equipment and for documenting the demonstration of such proficiency. The offer shall be made orally and in person when delivery occurs at the pharmacy. When delivery occurs outside of the pharmacy, whether by mail, vehicular delivery or other means, the offer shall be made either orally and in person, or by telephone from the pharmacist to the patient. If delivery occurs outside of the pharmacy, the pharmacist shall provide the patient with access to a telephone service that is toll-free for long-distance calls. A pharmacy whose primary patient population is accessible through a local measured or toll-free exchange need not be required to offer toll-free service. Counseling may be conducted by the provision of printed information in a foreign language if requested by the patient or representative. Professional judgment shall be exercised

in determining whether or not to offer counseling for prescription refills. **An offer to counsel shall be communicated in a positive manner to encourage acceptance.**

(c) In order to counsel patients effectively, a reasonable effort shall be made to obtain, record, and maintain significant patient information, including:

- (1) name, address, telephone number;
- (2) date of birth (age), gender;
- (3) medical history:
 - (A) disease state(s);
 - (B) allergies/drug reactions;
 - (C) current list on non-prescription and prescription medications, devices, and medical equipment.
- (4) comments relevant to the individual's drug therapy.

A "**reasonable effort**" shall mean a good faith effort to obtain from the patient or representative the foregoing patient information. Ancillary personnel may collect, record, and obtain patient profile information, but the pharmacist or person in charge of the facility holding the device and medical equipment permit must review and interpret patient profile information and clarify confusing or conflicting information. Professional judgment shall be exercised as to whether and when individual patient history information should be sought from other health care providers.

(d) Once patient information is obtained, this information shall be reviewed and updated by the pharmacist or person in charge of the facility holding the device and medical equipment permit before each prescription is filled or delivered, typically at the point-of-sale or point of distribution to screen for potential drug therapy problems due to:

- (1) therapeutic duplication;
- (2) drug-disease contraindication;
- (3) drug-drug interactions, including serious interactions with prescription or over-the-counter drugs;
- (4) incorrect drug dosage or duration of drug treatment;
- (5) drug-allergy interactions; and

(6) clinical abuse/misuse.

(e) Unless refused by the patient or representative, patient counseling shall be provided as follows:

(1) **counseling shall be "face to face" by the pharmacist, or personnel of a device and medical equipment permit holder when possible;**

(2) alternative forms of patient information may be used to supplement patient counseling;

(3) **patient counseling, as described in this Rule, shall be required for outpatient and discharge patients of hospitals, health maintenance organizations, health departments, and other institutions; however, compliance with this Rule in locations in which non-pharmacists are authorized by law or regulations to dispense may be accomplished by such authorized non-pharmacists; and**

(4) patient counseling, as described in this Rule, shall not be required for inpatients of hospitals or other institutions where a nurse or other licensed health care professional administers the medication(s).

(f) Pharmacists that distribute prescription medication by mail, and where the practitioner-pharmacist-patient relationship does not exist, shall provide counseling services for recipients of such medication in accordance with this Rule.

(g) Records resulting from compliance with this Rule, including documentation of refusals to receive counseling, shall be maintained for three years in accordance with Section .2300 of this Chapter.

(h) Personnel of device and medical equipment permit holders shall give written notice of warranty, if any, regarding service after the sale. The permit holder shall maintain documentation demonstrating that the written notice of warranty was given to the patient.

(i) Offers to counsel and patient counseling for inmates need not be "face to face", but rather, may be conducted through a correctional or law enforcement officer or through printed material. A pharmacist or a device and medical equipment permit holder dispensing drugs or devices or delivering medical equipment to inmates need not comply with Paragraph (c) of this Rule. However, once such patient information is obtained, the requirements of Paragraph (d) of this Rule shall be followed.

****IMPORTANT POINT****

Patient counseling should be documented in writing and these records maintained for three years. Documentation may be made in the patient's medical record, on the prescription, or another designated form. If a patient refuses counseling, this must also be documented as described.

§ G.S. 131E-79.1. Counseling patients regarding prescriptions.

- (a) Any hospital or other health care facility licensed pursuant to this Chapter or Chapter 122C of the General Statutes, health maintenance organization, **local health department, community health center, medical office, or facility operated by a health care provider licensed under Chapter 90 of the General Statutes, providing patient counseling by a physician, a registered nurse, or any other appropriately trained health care professional shall be deemed in compliance with the rules adopted by the North Carolina Board of Pharmacy regarding patient counseling.**
- (b) **As used in this section, "patient counseling" means the effective communication of information to the patient or representative in order to improve therapeutic outcomes by maximizing proper use of prescription medications and devices.**

PHARMACY PERMIT REQUIREMENTS

Limited Service Pharmacy Permit. A pharmacy permit issued by the Board to an applicant that wishes to render in an institutional setting pharmaceutical services not limited to scope and kind but to time and conditions under which such services are rendered.

REGISTRATION AND PERMITS

- (a) **Registration Required.** All places providing services which embrace the practice of pharmacy shall register with the North Carolina Board of Pharmacy as provided in G.S. 90-85.21 and acquire a permit to do so. Application for such registration and permit shall be on forms provided by the Board. If the Board is satisfied that proper facilities and adequately trained and properly licensed personnel have been obtained which will assure compliance with all laws regulating the compounding and distribution of drugs, the practice of pharmacy and the rules of the Board, a permit shall be issued by the Board attesting such registration.
- (b) **Exemptions.** Nothing in these rules shall be construed to require the registration with the Board of those health care facilities in which there occurs only the administration of drugs.
- (c) **Separate Registration Required.** The dispensing of drugs from separate locations owned by a health care facility, such as satellite pharmacies, outside clinics, health maintenance organizations, or physician's offices owned by the health care facility shall require separate registration if any one of the following criteria exists:
 - (1) The drugs dispensed at the location are ordinarily and customarily obtained from a source outside of the health care facility;
 - (2) The pharmacist-manager is controlled and supervised from a source other than the health care facility pharmacy; or
 - (3) The routine activity at the location is dispensing drugs to outpatients.
- (d) Any pharmacy that provides compounding or dispensing services to one or more health care facilities for individual patient administration bearing any labeled name other than that under which it is registered shall require a separate registration.
- (e) Health care facilities, which do not have a pharmacy permit, shall secure their pharmaceutical services through a pharmacist holding a current license from the Board. [21 NCAC 46.1401]

PHYSICAL REQUIREMENTS FOR PERMIT

A health care facility pharmacy shall have sufficient floor space allocated to it to ensure that drugs are prepared in sanitary, well lighted and enclosed places. It shall have sufficient equipment and physical facilities for proper compounding, dispensing, and storage of drugs, including parenteral preparations. In addition to the requirements of Section .1600 of this Chapter, the equipment and physical facilities shall include the following:

- (1) Compounding and dispensing areas;
- (2) Physically separate parenteral solution additive area when parenteral solutions are compounded as described in Section .2800 - Sterile Parenteral Pharmaceuticals of this Chapter;
- (3) Receiving and storage areas;
- (4) Packaging and repackaging areas;
- (5) Office space sufficient to allow for administrative functions without interference with the safe compounding and dispensing of medications and security of the pharmacy;
- (6) Storage. All drugs shall be stored in designated areas within the pharmacy or decentralized pharmacy sufficient to provide sanitation to prevent contamination, moisture control, and security to prevent access from unauthorized personnel. Controlled substances shall be stored in compliance with applicable Federal and State laws and regulations. Alcohol and flammables shall be stored in areas that shall, at a minimum, meet basic local building code requirements for the storage of volatile substances and such other laws, ordinances, or regulations that may apply.
- (7) Security. All areas occupied by the health care facility pharmacy, to include auxiliary drug supplies and unit dose carts, shall remain secured at all times.

[21 NCAC 46.1412]

PHARMACY PERMITS (CON'T)

(a) Applications for pharmacy permits, whether original or renewal, shall be made upon forms provided by the Board. The Board shall not issue any original or annual renewal pharmacy permit until the Board is satisfied that:

- (1) The pharmacist-manager is sure that at all times adequate qualified personnel have been secured by the management of the store to properly render pharmaceutical service in the manner prescribed by law.
- (2) The pharmacy posts in a location conspicuous to the public the specific hours that a pharmacist is on duty in the pharmacy. This requirement does not apply to hospitals, nursing homes, and similar institutions subject to the provisions of Section .1400 of this Chapter.
- (3) The pharmacist-manager shall be responsible for obtaining and maintaining equipment in the pharmacy adequate to meet the pharmaceutical care needs of the pharmacy's patients. The pharmacy's reference library shall include a medical dictionary and current editions of generally accepted reference books on drug interactions, clinical pharmacology, USP Dispensing Information or its equivalent, and if IV admixture services are provided, a reference on Parenteral Incompatibilities.
- (4) The pharmacy is equipped with sanitary appliances including lavatory facilities with hot and cold running water; is adequately lighted; and is kept in a clean, orderly, and sanitary condition.
- (5) All prescription medications are labeled in accordance with G.S. 106-134 and 106-134.1.

(b) In addition to the requirements for issuance and renewal of a pharmacy permit imposed by statute and rules of the Board, a permit shall not be issued or renewed to any person to operate a pharmacy wherein the prescriptions of medical practitioners are compounded or dispensed and distributed when such distribution is effected by mail and the practitioner- pharmacist-patient relationship does not exist, until the Board is satisfied that:

- (1) The pharmacy maintains records of prescriptions compounded or dispensed and distributed in manner that is readily retrievable;
- (2) During the pharmacy's regular hours of operation but not less than six days per week, for a minimum of forty hours per week, a toll-free telephone service is provided to facilitate communication between patients and a pharmacist at the pharmacy who has access to the patient's records. This toll-free number must be disclosed on the label affixed to each container of dispensed drugs;
- (3) The pharmacy complies with all lawful orders, directions, and requests for information from the Boards of pharmacy of all states in which it is licensed and all states into which it distributes prescription drugs;
- (4) The pharmacy complies with all USP and FDA requirements regarding the storage, packaging, and shipping of prescription medications. The pharmacist- manager and all other pharmacists employed in the pharmacies

permitted pursuant to this Paragraph shall be subject to all Federal and State statutes and regulations concerning the dispensing of prescription medications including, but not limited to, 21 NCAC 46 .1801 and .1805 and 21 CFR 1306.01, 1306.05, and 1306.21.

(c) The Board shall not issue an original or renewal permit to any person to operate a drugstore or pharmacy as a department in or a part of any other business serving the general public (except hospitals, nursing homes, and similar institutions subject to the provisions of Section .1400 of this Chapter) unless such pharmacy facility:

- (1) is physically separated from such other business;
- (2) is separately identified to the public both as to name and any advertising;
- (3) completes all transactions relative to such pharmacy within the registered facility; and
- (4) meets the same requirements for registration as all other pharmacies.

(d) Permits to operate pharmacies, whether original or renewal, shall be issued to the pharmacist-manager of such pharmacy pursuant to a joint application of the owner and pharmacist-manager for the conduct and management of said pharmacy. The issuance of said permit shall not be complete and the permit shall not be valid until the pharmacist-manager as represented in the application has countersigned it. The permit so issued is valid only so long as the pharmacist-manager to whom it was issued assumes the duties and responsibilities of pharmacist-manager. Permits may be reissued at any time to a successor pharmacist-manager pursuant to the proper amendment of the application for the permit.

(e) Upon application, the Board may issue and renew separate permits for pharmacies operating at one location. Records for each permitted pharmacy must be maintained separately. Prior to issuance of an original permit, each pharmacy shall submit a plan to the Board that shall assure accountability for the actions of each pharmacy at the location.

[21 NCAC 46.1601]

REQUIREMENT OF PERSONAL APPEARANCE

Prior to issuance of any original permit or device and medical equipment permit, the following persons must appear personally at the Board office on the first Monday of the month, the Monday before the monthly Board meeting, or such other time as scheduled with the Board's staff:

- (1) the pharmacist-manager for the applicant pharmacy; and
- (2) the person in charge of the facility applying for the device and medical equipment permit.

[21 NCAC 46.1606]

Pharmacy permit.

In accordance with Board regulations, each pharmacy in North Carolina shall annually register with the Board on a form provided by the Board. The application shall identify the pharmacist-manager of the pharmacy and all pharmacy personnel employed in the pharmacy. All pharmacist-managers shall notify the Board of any change in pharmacy personnel within 30 days of the change. [G.S. 90-85.21]

License and permit to be displayed.

Every pharmacist-manager's license, every permit, and every current renewal shall be conspicuously posted in the place of business owned by or employing the person to whom it is issued. The licenses and every last renewal of all other pharmacists employed in the pharmacy must be readily available for inspection by agents of the Board. Failure to display any license or permit and the most recent renewal shall be a violation of this Article and each day that the license or permit or renewal is not displayed shall be a separate and distinct offense. [G.S. § 90-85.23]

RESPONSIBILITIES OF THE PHARMACIST-MANAGER

- The pharmacist-manager shall assure that prescription legend drugs and controlled substances are safe and secure within the pharmacy.
[21 NCAC 46.2502(a)]
- The pharmacist-manager shall maintain complete authority and control over any and all keys to the pharmacy and shall be responsible for the ultimate security of the pharmacy. A pharmacy shall be secured to prohibit unauthorized entry if no pharmacist will be present in the pharmacy for a period of 90 minutes or more. [21 NCAC 46.2502(e)]
- These duties are in addition to the specific duties of pharmacist-managers at institutional pharmacies and pharmacies in health departments (as set forth in the Rules in this Chapter.) [21 NCAC 46.2502(f)]
- A person shall not serve as pharmacist-manager at more than one pharmacy at any one time except for limited service pharmacies. [21 NCAC 46.2502(g)]
- The pharmacist-manager shall prepare a plan to safeguard prescription records and pharmaceuticals in the event of a natural disaster such as hurricane or flood. [21 NCAC 46.2502(j)]
- The pharmacist-manager shall separate from the dispensing stock all drug products more than six months out of date. [21 NCAC 46.2502(k)]
- The pharmacist-manager shall report to the Board of Pharmacy information that reasonably suggests that there is a probability that a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient or customer. This report shall be filed in writing on a form provided by the Board within 14 days of the owner representative or pharmacist-manager's becoming aware of the event. The pharmacist-manager shall retain all documents, labels, vials, supplies, substances and internal investigative reports relating to the event. All such items shall be made available to the Board upon request.
[21 NCAC 46.2502(l)]
- The Board shall not disclose the identity of a pharmacist-manager who makes a report under Paragraph (l) of this Rule, except as required by law. All reports made under Paragraph (l) of this Rule shall not be released except as required by law. [21 NCAC 46.2502(m)]
- Dispensing errors, which are not detected and corrected prior to the patient receiving the medication, shall be documented and reported to the pharmacist-manager. Documentation shall include pertinent chronological information

and appropriate forms including the identity of individual(s) responsible. These documents, including action taken as part of a quality assurance plan, shall be archived in a readily retrievable manner and open for review, copying or seizure by the Board or its designated employees within 48 hours of a request for inspection for a period of three years. These documents shall be released only to the Board or its designated employees pursuant to an investigation and shall not otherwise be released except as required by law. Upon request by the Board or its designated employees, these documents shall be transmitted by the pharmacist-manager to an office of the Board. [21 NCAC 46.2502(n)]

- In any Board proceeding, the Board shall consider compliance with Paragraphs (l) and (n) of this Rule as a mitigating factor and noncompliance with Paragraphs (l) and (n) of this Rule as an aggravating factor. [21 NCAC 46.2502(o)]
- All registrants under G.S. 90-85.21 shall develop and implement policies and procedures to insure that all out-dated, improperly labeled, adulterated, damaged or unwanted drugs or drug containers with worn, illegible or missing labels are destroyed or disposed of so as to render them unusable.
[21 NCAC 46.3001(a)]
- Upon notification of medication errors resulting from the administration of an incorrect medication or dose, the pharmacist-manager shall document such medication error. Documentation shall include pertinent chronological information and include documentation on health care facility forms. These documents shall be archived in a readily retrievable manner, open for inspection, for a period of three years. [21 NCAC 46.1414 (j)(2)]
- Upon notification of information that reasonably suggests that there is a probability a prescription drug or device dispensed from a location holding a permit has caused or contributed to the death of a patient, the pharmacist-manager shall retain all documents, labels, vial, supplies, substances and internal investigative reports relating to the event. All such items shall be maintained by the health care facility, accessible to the pharmacist-manager, and open to the Board of Pharmacy. [21 NCAC 46.1414 (j)(3)]
- The pharmacist in charge of a pharmacy shall report within 10 days to the Board any disaster, accident, theft, or emergency which may affect the strength, purity, or labeling of drugs and devices in the pharmacy.
[G.S. 90-85.25(b)]

ADULTERATED DRUGS (AND DEVICES)

A drug or device shall be deemed to be adulterated:

- (1) **a.** If it consists in whole or in part of any filthy, putrid or decomposed substance; or

b. If it has been produced, prepared, packed, or held under insanitary conditions whereby it may have been contaminated with filth, or whereby it may have been rendered injurious to health; or

c. If it is a drug and its container is composed, in whole or in part, of any poisonous or deleterious substance which may render the contents injurious to health; or

d. If:

 1. It is a drug and it bears or contains, for purposes of coloring only, a color additive which is unsafe within the meaning of G.S. 106-132, or
 2. If it is a color additive, the intended use of which in or on drugs is for purposes of coloring only, and is unsafe within the meaning of G.S. 106-132;

e. If it is a drug and the methods used in, or the facilities or controls used for, its manufacture, processing, packing, or holding do not conform to or are not operated or administered in conformity with current good manufacturing practice to assure that such drug meets the requirements of this Article as to safety and has the identity and strength, and meets the quality and purity characteristics, which it purports or is represented to possess.
- (2) If it purports to be or is represented as a drug the name of which is recognized in an official compendium, and its strength differs from, or its quality or purity falls below, the standard set forth in such compendium. Such determination as to strength, quality, or purity shall be made in accordance with the tests or methods of assay set forth in such compendium, or in the absence of or inadequacy of such tests or methods of assay, those so prescribed under authority of the federal act. No drug defined in an official compendium shall be deemed to be adulterated under this subdivision because it differs from the standard of strength, quality, or purity therefore set forth in such compendium, if its difference in strength, quality, or purity from such standard is plainly stated on its label. Whenever a drug is recognized in both the United States Pharmacopoeia and the Homeopathic Pharmacopoeia of the United States it shall be subject to the requirements of the United States Pharmacopoeia unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the Homeopathic Pharmacopoeia of the United States and not to those of the United States Pharmacopoeia.
- (3) If it is not subject to the provisions of subdivision (2) of this section and its strength differs from, or its purity or quality falls below, that which it purports or is represented to possess.
- (4) If it is a drug and any substance has been

 - a.** Mixed or packed therewith so as to reduce its quality or strength; or substituted wholly or in part therefore.[G.S. § 106-133]

MISBRANDED DRUGS (AND DEVICES)

A drug or device shall be deemed to be misbranded:

- (1) If it's labeling is false or misleading in any particular, or if it's labeling or packaging fails to conform with the requirements of G.S. 106-139 or 106-139.1 of this Article.
- (2) If in package form unless it bears a label containing
 - a. The name and place of business of the manufacturer, packer, or distributor; and
 - b. An accurate statement of the quantity of the contents...
- (3) If any word, statement, or other information required by or under authority of this Article to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with other words, statements, designs or devices, in the labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use.
- (4) If it is a habit-forming drug under these regulations and the label does not bear the statement: "Warning – May be habit forming."
- (5) If its label does not:
 - a. carry the established name of the drug (official name, compendia name or common name);
 - b. in the case of a drug fabricated from two or more ingredients, list the established name of each ingredient, the kind and quantity of alcohol, and the quantity or proportion of each listed ingredient, whether active or inactive;
 - c. in the case of a prescription drug, show the established name in letters at least half as high as those showing the proprietary or trade name of the drug;
- (6) Unless its labeling bears
 - a. Adequate directions for use; and
 - b. Such adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users.
- (7) If it is a drug listed in an official compendium, unless it is packaged and labeled as prescribed therein. Whenever a drug is recognized in both the United States Pharmacopoeia (USP) and the Homeopathic Pharmacopoeia of the United States (HPUS), it shall be subject to the requirements of the USP with respect to packaging and labeling unless it is labeled and offered for sale as a homeopathic drug, in which case it shall be subject to the provisions of the HPUS.

- (8) If it has been found by the Department of Agriculture and Consumer Services to be a drug liable to deterioration, unless it is packaged in such form and manner, and its label bears a statement of such precautions, as the Board of Agriculture shall by regulations require as necessary for the protection of public health.
- (9) a. If it is a drug and its container is so made, formed, or filled as to be misleading;
or
b. If it is an imitation of another drug; or
c. If it is offered for sale under the name of another drug.
- (10) If it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in the labeling thereof.
- (11) In the case of any prescription drug distributed or offered for sale in this State, unless the manufacturer, packer, or distributor thereof includes in all advertisements and other descriptive printed matter issued or caused to be issued by the manufacturer, packer, or distributor with respect to that drug a true statement of
- a. The established name, as defined in G.S. 106-134(5) b of this Article, printed prominently and in type at least half as large as that used for any trade or brand name thereof,
- b. The formula showing quantitatively each ingredient of such drug to the extent required for labels under section 502(e) of the federal act, and
- c. Such other information in brief summary relating to side effects, contraindications, and effectiveness as shall be required in regulations issued under the federal act.
- (12) If a trademark, trade name or other identifying mark, imprint or device of another or any likeness of the foregoing has been placed thereon or upon its container with intent to defraud.
- (13) If it is a drug and it's packaging or labeling is in violation of an applicable regulation issued pursuant to section 3 or 4 of the Federal Poison Prevention Packaging Act of 1970.

G.S. § 106-134.

VIOLATIONS

§ 90-85.40. Violations.

- (a) It shall be unlawful for any owner or manager of a pharmacy or other place to allow or cause anyone other than a pharmacist to dispense or compound any prescription drug unless that person is a pharmacy technician or a pharmacy student who is enrolled in a school of pharmacy approved by the Board and is working under the supervision of a pharmacist.
- (b) Every person lawfully authorized to compound or dispense prescription drugs shall comply with all the laws and regulations governing the labeling and packaging of such drugs by pharmacists.
- (c) It shall be unlawful for any person not licensed as a pharmacist to compound or dispense any prescription drug, unless that person is a pharmacy technician or a pharmacy student who is enrolled in a school of pharmacy approved by the Board and is working under the supervision of a pharmacist
- (d) It shall be unlawful for any person to manage any place of business where devices are dispensed or sold at retail without a permit as required by this Article.
- (dl) It is unlawful for a person to own or manage a place of business from which medical equipment is delivered without a permit as required by this Article.
- (e) It shall be unlawful for any person without legal authorization to dispose of an article that has been embargoed under this Article.
- (f) It shall be unlawful to violate any provision of this Article or of any rules or regulations enacted pursuant to it.
- (g) This Article shall not be construed to prohibit any person from performing an act that person is authorized to perform pursuant to North Carolina law Health care providers who are authorized to prescribe drugs without supervision are authorized to dispense drugs without supervision.
- (h) A violation of this Article shall be a Class 1 misdemeanor.

DISCIPLINARY AUTHORITY

§ 90-85.38. Disciplinary authority.

- (a) The Board may, in accordance with Chapter 150B of the General Statutes, issue a letter of reprimand or suspend, restrict, revoke, or refuse to grant or renew a license to practice pharmacy, or require licensees to successfully complete remedial education if the licensee has done any of the following:
- (1) Made false representations or withheld material information in connection with securing a license or permit.
 - (2) Been found guilty of or plead guilty or nolo contendere to any felony in connection with the practice of pharmacy or the distribution of drugs.
 - (3) Indulged in the use of drugs to an extent that renders the pharmacist unfit to practice pharmacy.
 - (4) Made false representations in connection with the practice of pharmacy that endanger or are likely to endanger the health or safety of the public, or that defraud any person.
 - (5) Developed a physical or mental disability that renders the pharmacist unfit to practice pharmacy with reasonable skill, competence and safety to the public.
 - (6) Failed to comply with the laws governing the practice of pharmacy and the distribution of drugs.
 - (7) Failed to comply with any provision of this Article or rules adopted by the Board.
 - (8) Engaged in, or aided and abetted an individual to engage in, the practice of pharmacy without a license.
 - (9) Been negligent in the practice of pharmacy.
- (b) The Board, in accordance with Chapter 150B of the General Statutes may suspend, revoke, or refuse to grant or renew any permit for the same conduct as stated in subsection (a).
- (c) Any license or permit obtained through false representation or withholding of material information shall be void and of no effect.

§ 90-85.39. Injunctive authority.

The Board may apply to any court for an injunction to prevent violations of this Article or of any rules enacted pursuant to it. The court is empowered to grant the injunctions regardless of whether criminal prosecution or other action has been or may be instituted as a result of the violation.

BLACK LETTER RULES

(American Law Reports)

- 1. A pharmacist must employ individuals who are capable of discriminating among drugs sold.**
- 2. A pharmacist must know the purposes of the drugs that he or she sells.**
- 3. A pharmacist must know the properties of the medicines that he or she sells.**
- 4. A pharmacist is not bound to fill any and all prescriptions; and his or her legal duty to a purchaser goes beyond merely dispensed the identical substance for which the prescription calls. He or she may know that the prescriber has erred in the prescription and that filling it might cause death or serious injury to the patient.**
- 5. A pharmacist cannot safely fill a prescription calling for doses that are obviously fatal, nor can he or she, when the doses prescribed by the physician appear to be unusual, safely fill the prescription without questioning the physician to make sure that no error has been made.**
- 6. The above should not be construed to say that a pharmacist can not safely fill a prescription because it is out of the ordinary, since patients conceivably could die from being denied unusual remedies in extreme cases.**
- 7. Upon discovery of a mistake, the pharmacist must see that it is promptly rectified.**
- 8. Illegibility of a physician's prescription is no defense for a pharmacist who uses a different drug from the one prescribed, in dispensing the prescription.**
- 9. If there is any doubt as to the identity of the drug ordered, it is the pharmacist's duty to take all reasonable precautions to be certain that one drug is not sold when another has been prescribed.**
- 10. A pharmacist has a duty to exercise ordinary care to discover defects in the drugs and medicines that he or she sells.**
- 11. A pharmacist is not required to analyze the contents of each individual bottle or package of nonprescription drugs furnished by the manufacturer.**
- 12. A pharmacist who, in filling a prescription, replaces the manufacturer's label on a prepackaged preparation with his or her own, must exercise an extremely high standard of care to ascertain that the drug dispensed is exactly that prescribed. The pharmacist is responsible for any observable deterioration of a prepackaged pharmaceutical.**

- 13. A pharmacist who knows that a drug, harmless in itself, is to be mixed or used in combination with another and the combination would have an injurious effect of which the purchaser would have no knowledge, should advise the purchaser. Failure to do so makes the pharmacist liable for the consequences.**
- 14. A pharmacist dealing in dangerous drugs owes to the public a duty to limit the danger by labeling or otherwise conveying potential hazards.**
- 15. A pharmacist's standard of care involves warning of dangers connected with the drugs and medicines he or she compounds and sells.**
- 16. A seller of drugs is required only to give a warning if he or she has knowledge of a dangerous ingredient or side effect or if, by application of reasonable, developed skill and foresight, he or she might suspect a hazard. This does not mean that a pharmacist is required to test independently a drug's chemical structure for side effects of other possible risks.**

APPENDIX I

**RELATIONSHIP BETWEEN THE PHARMACISTS,
PUBLIC HEALTH NURSES
AND
THE HEALTH DEPARTMENT ADMINISTRATION**

Separate functions

1. Role of the pharmacist manager:
 - A. Assure drug control and accountability
 - B. Serve as a source of drug information
 - C. Assure compliance with all laws and rules
 - D. Assist in training public health registered nurses for dispensing
 - E. Verify accuracy of pharmacy records
 - F. Update public health nurses regarding new dispensing requirements
 - G. Provide guidance, support, and feedback relating to problems.
2. Role of the public health nurse:
 - A. Comply with the control and accountability system
 - B. Inform pharmacist manager of any problems with system
 - C. Remain current with information and training necessary to dispense
 - D. Assist in training public health registered nurses for dispensing
 - E. Comply with all laws and rules
 - F. Maintain complete and current pharmacy records
3. Role of the health department administration:
 - A. Provide adequate resources for dispensing
 - B. Assist in compliance with control and accountability system

Joint functions

1. Policy and procedure development
 - A. Storage
 - B. Labeling
 - C. Packaging
 - D. Delivery of drugs and devices
 - E. Patient counseling
2. Quality Assurance
 - A. Error prevention
 - B. Review of system
 - C. System improvements

APPENDIX II

PROPER DISPENSING TECHNIQUES

1. Review the Prescription Order

- A. Check the prescription order to verify that it can be legally filled.**
- B. Check for completeness of the prescription order.**
- C. If necessary, obtain additional information**
- D. Verify the prescription order for the amount per dose, appropriate route, frequency, and duration of therapy.**
- E. Check patient record for pertinent information (e.g., allergies, potential drug interactions), and verify that the prescription is appropriate for the patient.**
- F. If a refill of the prescription order is requested, obtain necessary information from the patient and verify that the prescription can be legally refilled.**
- G. If any questions arise during this process, contact the pharmacist manager.**

2. Selecting Medication

- A. Determine if patient has taken medication before.**
- B. Determine source (manufacturer) of medication to be dispensed.**
- C. Document the source of the medication on the written prescription order (on hard-copy, patient's chart or medication drug record [e.g., TB])**
- D. Inspect the medication for defects.**
- E. Measure the appropriate quantity of medication**
- F. Verify that the correct medication was chosen before returning the source package to stock.**

3. Selecting Proper Containers

- A. Select the appropriate container for medication based upon size, storage requirements, lifestyle, and the need for a non-safety or child-resistant container. (Child-resistant containers are preferred.)**
- B. Transfer the measured number of units of medication to the prescription container.**
- C. Close or seal the container.**
- D. Write on the prescription order if a non-child resistant container was used.**

4. Labeling Containers

- A. Prepare the primary label, which meets legal requirements; contains clear, concise, comprehensive instructions to patient; and is legible.**
- B. Choose appropriate auxiliary labels.**
- C. Affix labels to container.**
- D. Note on prescription order which containers and auxiliary labels were used to insure consistent future packaging and labeling.**
- E. Note on prescription order the Rx serial number and your name.**
- F. Perform a final check of the finished prescription to ensure that all steps have been completed accurately.**

5. Obligations to Patient

- A. Evaluate medication for appropriate use.**
- B. Evaluate medication for appropriate length of therapy.**
- C. Evaluate patient information relative to appropriate therapy.**
- D. Recognize and remedy therapeutic problems such as:**
 - 1. Inappropriate of duplicate prescribing;**
 - 2. Iatrogenic and/or medication-induced illness;**
 - 3. Non-compliance with therapy; or**

- 4. Signs of medication misuse or abuse.**
- 5. Recognize and respond appropriately to precautions, warnings, and contraindications involving:**
 - a. Drug-drug interactions;**
 - b. Drug-disease interactions;**
 - c. Drug sensitivities and allergies;**
 - d. Genetic and/or environmental factors;**
 - e. Drug-food interactions;**
 - f. Adverse effects;**
 - g. Side effects; or**
 - h. Toxicities**
- 6. Counseling Patient**
 - A. Explain the name, description, and purpose of the medication;**
 - B. Explain the proper procedure for administering the medication, (e.g., dosage, method, time of day);**
 - C. Describe the principal side effects of the medication, and appropriate ways to minimize those effects;**
 - D. Explain cautions regarding food and/or drugs to avoid during therapy;**
 - E. Explain cautions for use by special populations, (e.g., geriatrics, pediatrics, diabetics, etc.);**
 - F. Explain the proper storage conditions for the medication;**
 - G. Explain refill information and action needed if dose is missed.**

APPENDIX III

RECOMMENDED REFERENCE LIBRARY

1. Medical dictionary, e.g., Dorland's
2. Medication reference, e.g. Drug Facts and Comparisons, or American Hospital Formulary Service
3. Drug interaction reference, **preferably a computerized program**, or books such as: Drug Interaction Facts, or Hansten's Drug Interactions
4. Patient information reference, e.g. USP Drug Information, or Patient Drug Facts
5. Pharmacology and therapeutics text, e.g., The Pharmacological Basis of Therapeutics (Goodman and Gilman), or Handbook of Applied Therapeutics;
6. Medical reference, e.g., The Merck Manual of Diagnosis and Therapy
7. Pharmacy Laws of North Carolina

Appendix IV

County Health Department
Medication Distribution Record

[illegible]